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MORRISON & FOERSTER LLP
12531 HIGH BLUFF DRIVE
SUITE 100
SAN DIEGO, CA 92130-2040

EXAMINER	
LEE, WILLIAM Y	

ART UNIT	PAPER NUMBER
1629	

NOTIFICATION DATE	DELIVERY MODE
06/10/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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PatentDocket@mofo.com
Drcaldwell@mofo.com

Office Action Summary	Application No.	Applicant(s)
	10/588,419	CURAUDEAU ET AL.
	Examiner	Art Unit
	WILLIAM LEE	1629

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *April 11, 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-13,18,19,22 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11-13,18,19,22 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)	
1) ☐ Notice of References Cited (PTO-892)	4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) ☐ Notice of Informal Patent Application
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.	6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Following the Reply filed on April 11, 2011 claims 1-9, 11-13, 18-19, 22 and 23 are pending in the instant application and are the subject of the Office Action below. In their response, applicants amended claims 1 and 23, while claims 14-17 were cancelled.

Claim Rejections- Withdrawn in view of Applicant's amendment/response

35 USC § 112, 2nd Paragraph

The previous grounds for rejection under 35 USC § 112, 2nd paragraph have been withdrawn in view of applicants' amendment of claims 1-9, 11-13, 18, 19, 22 and 23.

35 USC § 112, 1st Paragraph

The previous grounds for rejection under 35 USC § 112, 1st paragraph have been withdrawn in view of applicants' cancellation of claims 14-17.

Claim Rejections - 35 USC § 112

35 USC § 112, 2nd Paragraph, Indefinite rejections

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 11-13, 18, 19 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

Claim 1 recites the limitation "hydrophobic and/or lipophilic" and it is unclear what is exactly is meant by the term. As defined by applicants, "hydrophobic" is generally understood to refer to compounds with "a tendency not to combine with water, or are incapable of being substantially dissolved in water." (page 2, line 32 to page 3, line 1). It is noted that applicants further define as:

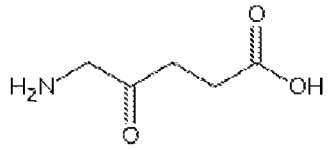
> One measure of hydrophobicity is the LogP value. In general, **substances having a LogP of 0 or greater are thought to be hydrophobic** while those with a negative LogP value are thought to be hydrophilic. It is preferred that the photosensitizer compositions used herein have a LogP of not less than 0, preferably not less than 0.5, more preferably not less than 0.75, even more preferably not less than 1.0. (page 3, lines 5-9).

Thus, applicants describe within their specification but not in claim 1, the term "hydrophobic" with sufficient clarity to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

Applicants use the limitation "lipophilic" to describe those compounds, (or in the instant application photosensitizers), that "have an affinity for, tend to combine with, or are capable of substantially dissolving in, lipids." (page 3, lines 2-3). Unlike the applicants' particular and distinct definition of hydrophobic (page 3 of specification), applicants' vague definition of lipophilic fails to particularly point out and distinctly claim the subject matter of applicants' invention. Upon reading the limitation of "lipophilic" in claim 1, the public is left to wonder to what extent the claimed "lipophilic" compounds have an affinity for, tend to combine with or are capable of "substantial" dissolution in lipids. Unlike the term hydrophobic, which can be measured and quantified by a LogP value, the term limitation "lipophilic" is not similarly quantifiable or capable of measurement with its definition found in applicants' specification. Therefore, applicant's invention is indefinite under the 35 U.S.C. 112, 2nd paragraph.

Claims 1-9, 11-13, 18, 19 and 22 are further rejected under 35 U.S.C. 112, second paragraph, as being indefinite with regard to the "analogs" of 5-aminolevulinic (also known as, δ-dALA, 5ala, ALA, or ALA).

Applicants amended claim 1 to recite the negative limitation "and analogs thereof", and it is unclear what is, or is not an analog of 5-ALA.



5-aminolevulinic acid

Applicants' specification provides no description or teaching of what analogs would be excluded by this negative limitation, thus leading to this indefiniteness rejection.

35 USC § 112, 1st Paragraph, Written Description rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 11-13, 18, 19 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the claims contain new matter. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' claims and their negative limitations

In particular, the negative limitations found in claim 1 (in bold):

- "hyperactive sebaceous gland disorders**, other than acne**" and the
- "photosensitizer is **other than 5-aminolevulinic acid and analogs thereof**"

lack adequate support in applicants' specification. These claim limitations were introduced by the applicants in their amended claims of May 5, 2009, see below:

1. (currently amended) A method to treat hyperactive sebaceous gland disorders, other than acne, in a subject by ~~which method comprises~~:

(i) topically applying a hydrophobic and/or lipophilic photosensitizer composition to skin tissue exhibiting symptoms of ~~acne~~ a hyperactive sebaceous gland disorder, and

(ii) exposing the tissue of said subject to light energy at a wavelength capable of activating the photosensitizer and at a fluence rate between about 0.1 mW/cm^2 and about $600mW/cm^2$,

wherein said photosensitizer is other than 5-aminolevulinic acid and derivatives thereof.

In their Amendment and Remarks of May 5, 2009, applicants alleged that support for these amended claim limitations "can be found, *inter alia*, in the claims as originally filed, page 8, lines 7-12 of the specification as originally filed, and at page 17, lines 24-26 of the specification as originally filed. Support for Claim 22 can be found, inter alia, in originally filed Claim 7."

Negative Limitations per the MPEP and the courts

In the past, courts have criticized negative limitations as an attempt to claim an invention "by excluding what [applicant] did not invent rather than particularly and distinctly point out what [applicant] did invent. *In re Schechter*, 204 F.2d 185, 98 U.S.P.Q. 144, 147 (C.C.P.A. 1953). This stark prohibition against negative limitations has shifted over the years, as noted by MPEP 2173.05(i), entitled **Negative Limitations**,

"[t]he current view of the courts is that there is nothing inherently ambiguous or uncertain about a negative limitation. So long as the boundaries of the patent protection sought are set forth definitely, albeit negatively, the claim complies with the requirements of 35 U.S.C. 112, second paragraph." Id. MPEP 2173.05(i) further states:

> Any **negative limitation** or **exclusionary proviso must** have **basis** in the **original disclosure**. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining."). See also *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), aff'd mem., 738 F.2d 453 (Fed. Cir. 1984). The **mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.** Note that a lack of literal basis in the specification for a negative limitation may not be sufficient to establish a prima facie case for lack of descriptive support. *Ex parte Parks*, 30 USPQ2d 1234, 1236 (Bd. Pat. App. & Inter. 1993).

Applicants' describe photosensitizers as follows:

> There are a variety of preferred synthetic and naturally occurring photo-sensitizers, **including**, but not limited to, pro-drugs such as the pro-**porphyrin 5-aminolevulinic acid (ALA**) and derivatives thereof, porphyrins and porphyrin derivatives e.g. chlorins, bacteriochlorins, isobacteriochlorins, phthalocyanine and naphthalocyanines and other tetra- and polymacrocyclic compounds, and related compounds (e.g. pyropheophorbides, sapphyrins and texaphyrins) and metal complexes (such as, but not limited by, tin, aluminum, zinc, lutetium). (page 8, lines 7-12)

The courts have made it quite clear on more than one occasion that support for each of the claim limitations **must be found within the four comers** of Applicants' disclosure – creation of a subgenus from a disclosure after the filing date of Applicants' application is not permissible. See *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1326, 56 USPQ2d 1481, 1486 (Fed. Cir. 2000) wherein the court stated, "*Ruschig* [referring to *In re Ruschig* 379 F.2d 990, 154 USPQ 118 (CCPA 1967)] makes clear that one cannot disclose a forest in the original application, and then later pick a tree out of

the forest and say "here is my invention." In order to satisfy the written description requirement, the blazemarks directing the skilled artisan to that tree must be in the originally filed disclosure."). ("[T]he specification does not clearly disclose to the skilled artisan that the inventors ... considered the ... ratio to be part of their invention .... There is therefore no force to Purdue's argument that the written description requirement was satisfied because the disclosure revealed a broad invention from which the [later-filed] claims carved out a patentable portion"). Id., at 1328.

See also *In re Johnson & Farnham*, where the court concluded that **one cannot introduce a new limitation, proviso or exclusion that was not originally disclosed at the time of filing from a larger generic conception. "The artificial subgenus thus created in the claims is not described in the parent case and would be new matter** if introduced into the parent case." *In re Johnson & Farnham*, 194 USPQ 187,192 (CCPA 1977). See also *In re Langdon*, the applicant in that case attempted to avoid a prior art reference by excluding nickel from a named group of metals claimed for a metallic protective coating. The court rejected the negative limitation claim "excepting nickel" because there was no distinguishable reason to exclude nickel from the named group. *In re Langdon*, 47 F.2d 920, 25 U.S.P.Q. 415 (C.C.P.A. 1935).

It is respectfully pointed out that there is no explicit recitation in applicants' specification of an embodiment of the invention where 5-ALA or analogs thereof are specifically excluded. Applicants' specification does not contain an embodiment or description of the claimed invention where the claimed method excludes 5-ALA from those photosensitizers. Rather, the specification (as highlighted above on page 8) describes use of 5-aminolevulinic acid as a preferred photosensitizer. However, the mere absence of a positive recitation of the negative limitation is not basis for an exclusion.

While there is no explicit prohibition against negatively excluding an alternative element recited in the specification such as 5-ALA, any negative limitation or exclusionary proviso must have basis in the original disclosure. Applicants have not provided basis for this negative limitation in their specification, nor have they pointed out where (as per their May 5, 2009 amendment) where in the specification their **negative limitation or exclusionary proviso** has **basis** in their originally filed specification.

With regard to treatment of diseases other than acne, applicants' specification does not contain an embodiment or description of the claimed invention where the claimed method excludes acne from the group of hyperactive sebaceous gland disorders to be treated. Applicants' Field of Invention states the invention is a method of using PDT and appropriate photosensitizers for treating hyperactive sebaceous gland disorders, especially acne. . . ." (page 1 lines 6-7). The specification is rife with preferred embodiments stating that acne is a disorder to be treated by applicants' claimed method of using PDT and a photosensitizer (see especially applicants' Example 2, pages 19-20).

Other than listing several species of non-acne hyperactive sebaceous disorders (seborrhea, seborrheic dermatitis and sebaceous gland hyperplasia), applicants' specification fails to define clearly delineate and define what other hyperactive sebaceous gland disorders that are excluded by the limitation "other than acne" and are subject to exclusion as defined by the negative "acne" limitation of claim 1.

Therefore, claims 1-9, 11-13, 18, 19 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the claims contain new matter.

Claim Rejections - 35 USC § 103 - Maintained

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9, 11-13, 18, 19, 22 and 23 are obvious over QLT and Kalka

The rejection of claims 1-9, 11-13, 18, 19, 22 and 23 as being unpatentable over QLT Inc. WO 031039597 A1 (N) and Kalka et al. (J Am Acad Dermatol. Mar. 2000) (U), is maintained.

Applicants contend that Kalka does not in fact teach the treatment of hyperactive sebaceous gland disorders, other than acne, by topically applying a photosensitizer composition to skin tissue of a subject in need thereof and exposing the tissue of the subject to light energy, as required by the claims. Applicants are further of the opinion that, Kalka mentions that "lipophilic propionibacteria has been utilized for

photodynamic destruction of these micro-organisms for the management of acne vulgaris. Repeated illumination with blue light at cumulative dose of 325 J/cm^2 resulted in marked reduction of both acne and seborrhea. [...] The possible value of topical PDT for benign inflammatory skin disease need further exploration." Kalka, page 403. Applicants states that Kalka teaches the destruction of lipophilic propionibacteria with **porphyrins** for management of acne vulgaris via use of blue light, and a resultant reduction in both acne and seborrhea. Kalka then suggests the possible value of PDT for benign inflammatory skin diseases and suggests further exploration (page 403, second column). Applicants believe that one of ordinary skill in the art would need to modify the teachings of QLT and Kalka so as to specifically treat hyperactive sebaceous gland disorders, other than acne, by topically applying a photosensitizer composition to skin tissue of a subject in need thereof.

The Examiner respectfully disagrees as applicants' remarks are misplaced. As previously stated, QLT Inc. teach a method of treatment of atopic dermatitis (page 15, lines 1-2, claim 13), and psoriasis (page 14, lines 28-30, claim 13) comprising administering a **photosensitizing agent** and li**ght energy** (page 2, lines 10-23). The photosensitizers will absorb radiation in the range of from 400 nm to 800 nm (page 3, lines 14-16) and include green porphyrins (page 3, line 31) such as the preferred BPD-MA (**verteporfin**) (page 4, lines 15-16) and QLT0074 (**lemuteporfin**) (page 6, lines 4-7). QLT Inc. teach treatment of psoriasis and atopic dermatitis but is silent with regard to treatment of seborrhea, seborrheic dermatitis or sebaceous gland hyperplasia.

Kalka et al. teach treatment of disorders such as **seborrhea** with porphyrins and illumination with blue light (page 403, column 2) and treatment of psoriasis with photodynamic therapy (PDT) using **photosensitizers** such as BPD-MA (**verteporfin**) (page 402, column 1). Applicants concede that Kalka teaches the treatment of both acne

and seborrhea. As explained above, sebaceous gland activity and the formation of acne go hand in hand as acne results from the obstruction and blockage of hair follicles and accompanying sebaceous gland by plugs of sebum produced by said gland.

Applicants suggest that Kalka does not teach topical application of a photosensitizer. In response to this suggestion, it is noted that QLT teaches topical application of photosensitizers BPD-MA (**verteporfin**) and QLT0074 (**lemuteporfin**). Per MPEP 2145, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references.

Further, Applicants have added the negative limitation to exclude the treatment of acne from their claimed method. The pathogenesis of acne involves the "formation of comedones, papules, pustules, nodules, and/or cysts as a result of **obstruction and inflammation of pilosebaceous units** (hair follicles and their **accompanying sebaceous gland**). . . . Acne occurs when **pilosebaceous** units become obstructed with plugs of **sebum** [produced by sebaceous glands] and desquamated keratinocytes. . . . " See The Merck Manual For Healthcare Professionals, section Acne Vulgaris (online version, www.merckmanuals.com/professionals, accessed June 2, 2011). Applicants' specification describes acne as an example of a hyperactive sebaceous gland disorders (page 3, lines 20-21). Applicants also describe and define other non-acne disorders to be treated (seborrhea, seborrheic dermatitis, or sebaceous gland hyperplasia) (page 3, lines 30-31). Sebaceous gland activity and the formation of acne go hand in hand with each other; acne results from the obstruction and blockage of hair follicles and accompanying sebaceous gland by plugs of sebum produced by said gland.

Due to the related nature and pathophysiology of acne and hyperactive sebaceous gland disorders, it would be obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Kalka with that of QLT to render the

claimed invention obvious. Thus contrary to applicants belief, the combined teachings of QLT and Kalka read upon the claimed invention as taught in the preamble and body of claim, i.e., the method of treating hyperactive sebaceous gland disorders, other than acne, by topically applying a photosensitizer composition to the skin of a subject in thereof.

With regard to motivation, applicants contends that nothing in QLT or Kalka teaches, suggests the claimed method; further, applicants contend that absent a teaching or suggestion of their method, one of ordinary skill in the art would find no motivation to perform the claimed method for treating hyperactive sebaceous gland disorders, **other than acne**. On the contrary, sebaceous gland activity (formation of sebum) and the formation of acne go hand in hand as acne results from the obstruction and blockage of hair follicles and accompanying sebaceous gland by plugs of sebum. One of ordinary skill in the art would be motivated to attempt to treat sebaceous gland activity disorders as it relies upon the same basic etiology as the formation of acne on the skin of a subject so afflicted.

Accordingly, it is clear that QLT in view of Kalka renders the claimed method obvious at the time of invention. Therefore, the rejection is maintained.

Reiterated Rejection:

Claims 1-9, 11-13, 18, 19, 22 and 23 were rejected under 35 U.S.C. 103(a) as being unpatentable over QLT Inc. WO 031039597 A1 (N) and Kalka et al. (J Am Acad Dermatol. Mar. 2000) (U).

The present independent claims are directed to methods for treating hyperactive sebaceous gland disorders, other than acne, in a subject in need thereof, the method comprising topically applying a photosensitizer composition to skin tissue of said subject

exhibiting symptoms of a hyperactive sebaceous gland disorder and exposing the tissues of said subject to light energy.

QLT Inc. teach a method of treatment of atopic dermatitis (page 15, lines 1-2, claim 13), and psoriasis (page 14, lines 28-30, claim 13) comprising administering a photosensitizing agent and light energy (page 2, lines 10-23). The photosensitizers will absorb radiation in the range of from 400 nm to 800 nm (page 3, lines 14-16) and include green porphyrins (page 3, line 31) such as the preferred BPD-MA (verteporfin) (page 4, lines 15-16) and QLT0074 (lemuteporfin) (page 6, lines 4-7).

Addressing instant claim 2, drawn to disorders such as seborrhea, seborrheic dermatitis or sebaceous gland hyperplasia, QLT Inc. teach treatment of psoriasis and atopic dermatitis but is silent with regard to treatment of seborrhea, seborrheic dermatitis or sebaceous gland hyperplasia. However, Kalka et al. teach treatment of disorders such as seborrhea with porphyrins and illumination with blue light (page 403, column 2) and treatment of psoriasis with photodynamic therapy (PDT) using photosensitizers such as BPD-MA (verteporfin) (page 402, column 1).

It would have been obvious to one of ordinary skill in art at the time it was made to employ the method of treatment of hyperactive sebaceous gland comprising administering photosensitizing compositions and exposing the subject to light energy motivated by the teaching of Kalka and QLT Inc. that teach both psoriasis and seborrhea are well known to be treated with porphyrins and light energy.

Addressing instant claim 3, drawn to a lipophilic photosensitizer, QLT Inc. teach that BPD-MA is a lipophilic and potent photosensitizer. Conversely, if a substance is lipophilic (fat-loving) then it is by token, hydrophobic, addressing instant claim 4).

Addressing instant claims 5 and 6, drawn to a photosensitizer that is inter alia, a porphyrin, QLT Inc. teach that BPD-MA and QLT0074 are "green porphyrins".

Addressing instant claim 7 drawn to the photosensitizer selected from verteporfin lemuteporfin or a combination thereof, QLT Inc. teach that the green porphyrins can be used in combination (page 7, lines 10-17).

Addressing instant claim 8, drawn to a viscosity at 20℃ of from about 50 cps to about 50000 cps, QLT Inc. teach a viscosity of from about 50 cps to about 50000 cps at 20° C (page 9, lines 24- 27).

Addressing instant claim 9, drawn to the method wherein excess photosensitizer is removed from the skin prior to application of energy, QLT Inc. teach that the composition is washed after allowing time for the photosensitizer to penetrate the stratum corneum and then irradiated with activation energy at an appropriate wavelength (page 12, line 20 to page 13, line 11).

Addressing instant claims 11-13, drawn to repeat of steps i and ii about every 6 months, about every 3 months and not less than about 5 days, QLT Inc. is silent as to how often the treatment method is repeated. However, one having ordinary skill in the art at the time the invention was made would be motivated to repeat the treatment as necessary. Since QLT Inc. teaches a treatment and not a cure, it is prima facie obvious to repeat the treatment as necessary and it is within the purview of the artisan to determine and optimize the period between doses.

Regarding the limitations of instant claims 1 and 23, drawn to the amount of light energy at a wavelength capable of activating the photosensitizer (claim 1) or lemuteporfin (claim 23) at a fluence rate between about 0.1 mWlcm2 and 600 mWlcm2, QLT Inc. teach absorption in the range of from 400 nm to 800 nm, typically from 600 nm to 750 nm (page 3, lines 14-16) with a specific example of BPD-MA that absorbs light at about 692 nm wavelength (page 4, lines 15-18). Although QLT Inc. does not teach the wavelength capable of activating the photosensitizer at a fluence rate between about 0.1

mWlcm2 and 600 mWlcm2, as noted in *In re Best*, (195 USPQ 430 (CCPA 1977)), and *In re Fitzgerald*, (205 USPQ 594 (CCPA 1980)), the mere recitation of newly-discovered function or property, inherently possessed by things in prior art, does not cause claims drawn to those things to distinguish over prior art. In such a situation, the burden is shifted to the applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same.

Addressing instant claims 17 and 18 drawn to an energy that is supplied by a light emitting diode device and the device emits red and blue light, Kalka et al. teach that diode lasers are employed to produce red light in the range of 770 to 850 nm (page 395, column I) and teach that photodynamic management of dermatologic conditions is simplified by the accessibility of the skin to light application and leaves the option to use any light device with the appropriate spectrum corresponding to the absorption maximum of the photosensitizing compound (page 394, column 2). Further, QLT teaches use of any suitable light source to activate the photosensitizer (page 1, lines 9-14) and teach that photosensitizers generally absorb radiation in the range of from 400 nm (about the range of blue light) to 800 nm (about the range of red light) (page 3, lines 14-16).

A reference is good not only for what it teaches by the direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re Opprecht*, 12 USPQ2d 1235, 1236 (Fed. Cir. 1989); *In re Bode*, 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi*, 215 USPQ 569 (CCPA

1982). In light of the foregoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. § 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

In summary, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM LEE whose telephone number is (571)270-3876. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey S. Lundgren can be reached on 571-272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/WILLIAM LEE/
Examiner
Art Unit 1629

/Jeffrey S. Lundgren/

Supervisory Patent Examiner, Art Unit 1629